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10/642,768	08/18/2003	Alexander V. Kukhtin	21416-93965	5089

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1634

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/642,768

Applicant(s)

KUKHTIN ET AL.

Examiner

BJ Forman

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5 and 7-37 is/are pending in the application.
- 4a) Of the above claim(s) 16-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5 and 7-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

FINAL ACTION

Status of the Claims

1. This action is in response to papers filed 3 April 2008 which claim 1 was amended and the previous rejections were traversed. The amendments have been thoroughly reviewed and entered. Applicant's arguments have been thoroughly reviewed, but are not found persuasive as discussed below

The previous rejections in the Office Action dated 3 January 2008 under 35 U.S.C. 112, first paragraph are withdrawn in view of the amendments. The previous rejections under 35 U.S.C. 103(a) are maintained.

Claims 1, 3-5, 7-15 are under prosecution.

Claim Interpretation

2. The preamble of the claim has been amended to define the macroporous polymer substrate as "having a macroporous substrate with a polymer size for molecular analysis based on a molecular weight of a specific molecule". The method steps do not define the "specific molecule". The method steps do not define a polymer size. The method steps do not define selection of a polymer, polymer size or polymer composition based on any molecule. Because the method steps do not define any molecule or polymer selection based on that molecule, the polymer size as recited in the preamble is given it broadest reasonable interpretation to encompass any macroporous polymer substrate made by the methods steps as recited in steps a-c of Claim 1.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 3-5, 7-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chang et al (U.S. Patent No. 6,994,964, filed 31 August 2000) and Chromecek et al (Patent Specification 1,188,736, published 22 April 1970, London England).

Regarding Claim 1, Chang et al disclose a method for making a microarray with a macroporous polymer substrate (Column 13, lines 11-18 and Example 1-2), the method including obtaining a monomers (e.g. HEMA, Columns 13-15) to form a polymerization mix in the presence of a porogenic solvent (i.e. aliphatic alcohol Column 15, lines 50-62 as defined in the instant specification, ¶ 20) coating a surface with the substrate (e.g. glass or silicon, Column 21, lines 25-56) and adding biomolecules to the coated surface to form an array (Examples 1-3) and wherein the pore size is controlled by the composition of the polymerization mixture (Column 12, lines 21-28).

Chang is silent regarding the mono and polyfunctional monomers forming the polymerization mixture wherein the size of the macropores is provided by the volumes of porogenic solvent. However, it was well known in the art at the time the claimed invention was made that pore size is controlled by the amount of aromatic alcohol in the polymerization mixture as taught by Chromecek (page 2, lines 85-94, page 3, lines 15-26, 58-64).

Chromecek teach a macroporous polymer supporting substrate comprising mixing mono and polyfunctional monomers and initiating polymerization in the presence of porogenic solvent (page 1-4). Chromecek further teach the polymeric support provides "permanent macroporous structures which are advantageous for detecting and separating polar compounds (page 1, line 35-48)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the monomers and solvent-controlled pores as taught by Chromecek to the porous substrate of Chang. One of ordinary skill in the art would have been motivated to do so for the expected benefits of "permanent macroporous structures which are advantageous for detecting and separating polar compounds as taught by Chromecek (page 1, line 35-48)

Regarding Claim 3, Chang et al disclose the method further comprising obtaining at least one immobilization chemical for linking biomolecules to the substrate (e.g. activating group) and adding the chemical to the substrate (Column 5, lines 3-16).

Regarding Claim 4, Chang et al disclose the method wherein the surface is glass or silica (Column 2, lines 4-6).

Regarding Claim 5, Chang et al disclose the method wherein biomolecules (e.g. DNA, proteins, peptides, lipids, polysaccharides, etc) are immobilized on the surface (Column 16, lines 24-35).

Regarding Claim 7, Chang et al disclose the method wherein the monofunctional methacrylate is e.g. an alkyl, methacrylates, (Column 2, lines 10-33 and Column 6, lines 42-67).

Regarding Claim 8, Chang et al disclose the method wherein the polyfunctional methacrylate is di-methacrylate i.e. branched (Column 2, lines 10-33 and Column 6, lines 42-67).

Regarding Claim 9, Chang et al disclose the method wherein the methacrylate is HEMA (Example 1, Column 21, lines 25-56 Column 27, lines 5-15).

Regarding Claims 10-11, Chang et al disclose the method wherein the porogenic solvent is an alcohol (Column 15, lines 50-52) but do not teach the aromatic alcohol. However, Chromecek teaches the similar polymer wherein the preferred solvent is a cyclo-alcohol (page 1, lines 65-66).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the aliphatic alcohol solvent of Chang with the cyclo-alcohol solvent of Chromecek. One of ordinary skill in the art would have been motivated to do so based on the similar functionality and well known use taught by Chromecek (page 1, lines 63-66).

The courts have stated that selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327. 65 USPQ 297. and In re Leshin, 227 F.2d. 197, 125 USPQ 416 (MPEP § 2144.07).

Regarding Claim 12, Chang et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 15, lines 50-52).

Regarding Claim 13, Chang et al disclose the method wherein the porogenic solvent is an aromatic alkyl derivative (Column 15, lines 21-62).

Regarding Claim 14, Chang et al disclose the method wherein the immobilization chemical is derivatized to include succinimide (Column 5, lines 10-16).

Regarding Claim 15, Chang et al disclose the method wherein the immobilization chemical is N-hydroxysuccinimide ether (Column 5, lines 10-16).

Response to Arguments

5. Applicant asserts that Chang and Chromecek would not be combined by those of skill in the art. To support this assertion, Applicant states that the Chang patent is about polymer brushes which is not the same as porous matrix or cross-linked polymer gel as instantly claimed. Applicant further asserts that one of skill would not combine Chan with the art of porous matrices because Chang was to be an improvement over porous matrices.

The arguments have been considered but are not found persuasive because, as cited above the text of the office action, Chang teaches all the method steps and components as recited in steps a-c. The instant claims neither exclude polymer brushes, nor define a porous matrix or cross-linked polymer gel to distinguish the claims over the polymer substrate as taught by Chang and Chromecek. Therefore, Applicant's arguments regarding the cross-linked polymer gel are not commensurate in scope with the claims. The claims merely require obtaining and mixing monomers in the presence of a porogenic solvent and initiating polymerization for form a macroporous polymer. The combination of Chang and Chromecek teach the method as claimed and detailed above.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

6. Claims 1, 3-5, 7-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (U.S. Patent No. 4,352,884, issued 5 October 1982) in view of Hammen et al (U.S. Patent Application Publication No. 2002/0043499, published 18 April 2002) and Chromecek et al (Patent Specification 1,188,736, published 22 April 1970, London England).

Regarding Claim 1, Nakashima et al disclose a method for making a microarray with a macroporous polymer substrate (Abstract, Column 3, lines 9-12 and Example 1-2), the method including obtaining mono and polyfunctional monomers (e.g. HEMA and GMA, Example 1) to form a polymerization mix in the presence of a porogenic solvent (i.e. aliphatic alcohol, Example 1) coating a surface with the substrate (Column 2, lines 48-58) and adding biomolecules to the coated surface to form an array (Column 3, lines 12-55) and wherein the pore size is controlled by the composition of the polymerization mixture (Column 12, lines 21-28).

Nakashima is silent regarding the size of the macropores being provided or controlled by the volumes of porogenic solvent. However, it was well known in the art

at the time the claimed invention was made that pore size is controlled by the amount of aromatic alcohol in the polymerization mixture as taught by Chromecek (page 2, lines 85-94, page 3, lines 15-26, 58-64).

Chromecek teach a macroporous polymer supporting substrate comprising mixing mono and polyfunctional monomers and initiating polymerization in the presence of porogenic solvent (page 1-4). Chromecek further teach the polymeric support provides "permanent macroporous structures which are advantageous for detecting and separating polar compounds (page 1, line 35-48)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to apply the monomers and solvent-controlled pores as taught by Chromecek to the porous substrate of Nakashima. One of ordinary skill in the art would have been motivated to do so for the expected benefits of "permanent macroporous structures which are advantageous for detecting and separating polar compounds as taught by Chromecek (page 1, line 35-48).

Nakashima et al further teach the macroporous support is for the immobilization of bioactive materials and specifically teaches biomolecule immobilization (Abstract, Column 3) but they are silent regarding immobilizing to form a microarray. However, macropolymer supports for immobilizing biomolecules to form a microarray were well known at the time the claimed invention was made as taught by Hammen.

Hammen teaches a similar method of polymerization of monomers to form a macroporous polymer support (Examples) having immobilized biomolecules wherein the preferred support is in the form of an array thereby providing for massively parallel

analysis (§ 74). It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the immobilization of Nakashima by immobilizing the biomolecules in an array format. One of ordinary skill in the art would have been motivated to do so for the expected benefit of thereby providing for massively parallel analysis of the biomolecules as desired in the art as taught by Hammon (§ 74).

Regarding Claim 3, Nakashima et al disclose the method further comprising obtaining at least one immobilization chemical for linking biomolecules to the substrate and adding the chemical to the substrate (Column 3, lines 54-68).

Regarding Claim 4, Nakashima et al disclose the method wherein the surface is glass or silica, plastic, vinyl (Column 2, lines 547-58).

Regarding Claim 5, Nakashima et al disclose the method wherein biomolecules (e.g. DNA, proteins, peptides, lipids, polysaccharides, etc) are immobilized on the surface (Column 3, lines 13-32).

Regarding Claim 7, Nakashima et al disclose the method wherein the monofunctional monomer is HEMA (Example 1, Column 6, lines 63-68).

Regarding Claim 8, Nakashima et al disclose the method wherein the polyfunctional monomer is di-methacrylate glycidyl methacrylate (Example 1, Column 6, lines 63-68).

Regarding Claim 9, Nakashima et al disclose the method wherein the methacrylate is HEMA and glycidyl methacrylate (Example 1, Column 6, lines 63-68).

Regarding Claims 10-11, Nakashima et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 6, lines 63-68) but do not teach the aromatic alcohol. However, Chromecek teaches the similar polymer wherein the preferred solvent is a cyclo-alcohol (page 1, lines 65-66).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the aliphatic alcohol solvent of Chang with the cyclo-alcohol solvent of Chromecek. One of ordinary skill in the art would have been motivated to do so based on the similar functionality and well known use taught by Chromecek (page 1, lines 63-66).

The courts have stated that selection of a known material based on its suitability for its intended use supported a prima facie obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327. 65 USPQ 297. and In re Leshin, 227 F.2d. 197, 125 USPQ 416 (MPEP § 2144.07).

Regarding Claim 12, Nakashima et al disclose the method wherein the porogenic solvent is an aliphatic alcohol (Column 6, lines 63-68).

Regarding Claims 14-15, Nakashima et al disclose the method wherein the immobilization chemical is N-hydroxysuccinimide ether (Column 3, lines 65-68).

Response to Arguments

Applicant asserts that Nakashima does not disclose any method for making a microarray. Applicant asserts that "microarrays" are well known in the art as e.g. miniaturized arrays of different biomolecules. Applicant acknowledges that Nakashima immobilizes biomolecules on a substrate but asserts that the resulting substrates are

not microarrays as known in the art. Applicant provides several website that provide information regarding microarray. The argument has been considered but is not found persuasive. The instant claims do not define a size (e.g. miniaturized) or biomolecule composition (e.g. different biomolecules) so as to define the instantly claimed method over that of the cited art. The claims merely require steps a-c of obtaining a macroporous polymer substrate, coating a surface with the substrate, and adding a plurality of the specific biomolecule to the coated surface. As such, Applicant's arguments regarding size and multiplexity are not commensurate in scope with the claims.

Applicant further asserts that a porogenic solvent is one which dissolves the monomer mixture being polymerized but does not dissolve the polymer, but not just any solvent containing alcohol as taught by Nakashima. The argument has been considered but is not found persuasive because instant claim 12 defines the porogenic solvent as an aliphatic alcohol, which is taught by Nakashima. Applicant's assertion that the alcohol of Nakashima would not work, is not sufficient to overcome the rejection because the assertion is not supported by any evidence of inoperability. As such, the argument is deemed unsupported arguments of counsel. Applicant is advised that this is not to be considered an invitation to file a declaration because a declaration submitted after final would not be deemed timely (37 C.F.R. 1.116(e)).

The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an

appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. (see (MPEP 716.01(c))).

Applicant further asserts that Hammen does not cure the deficiencies of Nakashima because Hammen does not teach formation of a porous polymer using porogenic solvents. The argument has been considered but is not found persuasive because the combined teachings as discussed above are not deemed deficient. It is maintained that the invention, as claimed, is obvious in view of the cited art. The rejections are maintained and made final.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BJ Forman
Primary Examiner
Art Unit 1634

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